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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,635	03/24/2004	Jun Feng	SYR-DPPIV-5004-U	8938
32793	7590	12/20/2005	EXAMINER	
TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			HABTE, KAHSA Y	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/809,635

Applicant(s)

FENG ET AL.

Examiner

Kahsay Habte

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-111 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 9, 11-17, 19, 23, 26, 27, 29, 37-39, 51-57, 83, 84, 95 and 99 is/are rejected.
- 7) ☒ Claim(s) 111 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 6,7,10,18,20-22,24,25,28,30-36,40-50,58-82,85-94,96-98 and 100-110.

DETAILED ACTION

1. Claims 1-111 are pending in this application.

Election/Restriction

2. Applicant's election of a single species: 2-[2-(3-Amino-piperidin-1-yl)-6-fluoro-4-oxo-4H-quinazolin-3-ylmethyl]-benzonitrile (Example 6 disclosed at page 115 of the specification) filed 11/30/2005 is acknowledged. Claims 1-5, 8-9, 11-17, 19, 23, 26-27, 29, 37-39, 51-57, 83-84, 95, 99 and 111 are readable thereon. Claims 6-7, 10, 18, 20-22, 24-25, 28, 30-36, 40-50, 58-82, 85-94, 96-98 and 100-110 are drawn to non-quinazoline compounds, stand withdrawn from further consideration as not being readable on the elected species. Since the elected species is free of prior art, the search was extended.
3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action. It is recommended that applicants amend the claims as:

Q = CO, CS, C=NR₉; R₃ and R₄ taken together to form a benzo ring; R₂ = azetidiny, pyrrolidiny, piperidiny or azepanyl (see claim 23); and R₁ = ZR_m where Z = (CH₂)₁₋₆ and R_m = phenyl.

Note that many of the species in claim 111 are drawn to non-elected invention. It is recommended that applicants delete these species e.g. 2,4-Dichloro-quinazoline.

Information Disclosure Statement

4. Applicant's Information Disclosure Statement, filed on 9/14/2005 and 8/2/2005 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 8-9, 11-13, 15-17, 19, 23, 26-27, 29, 34, 37-39, 83-84, 95 and 99 are rejected under 35 U.S.C. 102(a) as being anticipated by Kesarwani et al. *Tetrahedron Letters* 43 (2002) 5579-5581. Cited reference discloses a compound of interest: 3-(phenylmethyl)-2-[4-(phenylmethyl)-1-piperidinyl]-4(3H)quinazolinone at page 5580 that is the same as applicants when applicant's Formulae X, XI, XVIIa, XVIIb and XVIIc have the following substituents:

Q = CO; R₁ = benzyl (i.e. Z = CH₂ and R_m = phenyl); and R₂ = piperidinyl substituted with benzyl.

The examiner has attached an STN CAS search printout that shows the chemical structure of said species.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 8-9, 11-17, 19, 23, 26-27, 29, 37-39, 51-57, 83-84, 95 and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claim 1 and claims dependent thereon are rejected because the term “substituted” is indefinite. In the absence of the specific moieties intended to effectuate modification by the “substitution” or attachment to the chemical core claimed, the term “substituted” renders the claims in which it appears indefinite in all occurrences wherein applicants fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicants regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

b. In claim 1, the phrase “R₃ and R₄ are taken together to form...5 or 6-membered ring” is indefinite. What is the nature of the ring? What is covered and what is not? It is recommended that applicants amend the claim as “R₃ and R₄ are taken together to form...a benzo ring”.

Art Unit: 1624

c. In claim 1, the phrase "Z is a moiety providing 1-6 atom separation" is indefinite. What is covered and what is not? It is recommended that applicants amend the claim as suggested in 3.

d. In claim 16, the choices for R_1 are recited as " $\text{CH}_2\text{-NH}_2$, $\text{CH}_2\text{-OH}$, $\text{CH}_2\text{-(C3-7)alkyl}$, $\text{CH}_2\text{-alkene}$, $\text{CH}_2\text{-alkyne}$, $\text{CH}_2\text{-CCH}$ ", but said choices lack antecedent basis. Note that R_m is always a ring.

Likewise the same problem exists in claim 13, because of the choices for $R_m = \text{NH}_2$, OH , $(\text{C3-7})\text{alkyl}$, -alkene , -alkyne , or -CCH .

e. Claim 17 is improperly dependent on claim 1, because of the recitation of many heteroaryl rings for the choices of R_1 e.g. $=\text{O-heteroaryl}$, $\text{-O-heterobicycloaryl}$, etc. Note that R_1 is defined as aryl or cycloalkyl in claim 1.

f. In claim 17, the term "aminoaryl" is not clear. What is it? Is it an aryl group substituted by amino e.g. phenyl-NH_2 or is it a heteroaryl group with a nitrogen atom e.g. pyridyl?

g. In claim 17, the phrase "bicycloaryl" is not clear. What is it? Is naphthalene considered as bicycloaryl? How is it different from aryl? Note that aryl embraces aryl rings that are monocyclic e.g. phenyl or polycyclic e.g. anthracene.

Likewise, the same problem exists in claim 17 because of the recitation of "heterobicycoaryl" or "aminoheterobicyloaryl". What is covered by "heterobicycoaryl" or "aminoheterobicyloaryl" and what is not?

Objection

7. Claim 111 is objected to as being drawn to multiple inventions, but would be allowable if applicants limit the species to quinazolines delete the non-quinazoline derivatives i.e. Q = CO, CS, C=NR₉; R₃ and R₄ taken together to form a benzo ring; R₂ = azetidiny, pyrrolidinyl, piperidinyl or azepanyl (see claim 23); and R₁ = ZR_m where Z = (CH₂)₁₋₆ and R_m = phenyl.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

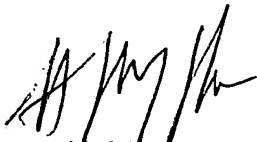
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1624

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kahsay Habte', is positioned above the printed name.

Kahsay Habte
Primary Examiner
Art Unit 1624

December 7, 2005